



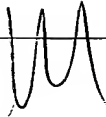
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/700,449	11/05/2003	Nicholas A. Sceusa	SCEUSA4A	6394
1444	7590	09/23/2004	EXAMINER	
BROWDY AND NEIMARK, P.L.L.C. 624 NINTH STREET, NW SUITE 300 WASHINGTON, DC 20001-5303			LEWIS, KIM M	
			ART UNIT	PAPER NUMBER
			3743	

DATE MAILED: 09/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/700,449	Applicant(s) SCEUSA, NICHOLAS A. 	
	Examiner Kim M. Lewis	Art Unit 3743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input checked="" type="checkbox"/> Other: <u>Detailed Action</u> . |

DETAILED ACTION

Double Patenting

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 1-12 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3 and 10-18 of copending Application No. 10/832994 ("the '994 application"). Although the conflicting claims are not identical, they are not patentably distinct from each other because the only differences in the claims are that the instant invention claims recite a "bandage" (claims 1-12), "a bioactive agent which delivers a pharmaceutically effective amount of the bioactive agent to a wound site" (claims 1 and 7) and "multiple bioactive agents" (claims 4 and 10) while the claims of the '994 application recite a "dressing" (claims 1-3 and 10-18), "at least one bioactive agent which delivers a pharmaceutically effective amount of the bioactive agent to a wound site" (claims 1 and 13) and "at least two

bioactive agents" (claim 10). Since a bandage is encompassed in the broad terminology of a dressing, a bioactive agent is encompassed in the broad terminology of at least one bioactive agent, and since multiple bioactive agents is encompassed in the broad terminology of at least two bioactive agents, the claims of the instant invention are anticipated by the claims of the '994 application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1 and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 4,728,323 ("Matson").

As regards claims 1 and 7, Matson discloses antimicrobial wound dressings, which anticipate applicant's claimed invention. More specifically Matson discloses a bandage (dressing) impregnated with bioactive agents. Once placed on the wounds the bioactive agents (e.g. silver sulfphadiazine) are released into the wound. Although not stated it is commonly known that the acid and base (ph)/(cation and anion) principles allow the silver ions from the silver salts to be released into the wound, thereby intrinsically meeting applicant's claim limitations.

Claim Rejections - 35 USC § 103

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claims 2, 3, 8 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Matson.

As regards claims 2, 3, 8 and 9, Matson fails to specifically teach the bioactive agent is a clot-promoting agent or antibiotic. However, the application of any type of bioactive agent, including a clot-promoting agent or an antibiotic, to the dressing of Matson for release at the wound site and operating under the previously stated principle would have been within the level of ordinary skill in the art.

7. Claims 4-6 and 10-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Matson in view of U.S. Patent No. 4,919,648 ("Sibalis").

As regards 4 and 10, note the rejection of claims 1 and 7 above. Matson fails to teach that the bandage (dressing) is impregnated with multiple bioactive agents. However, Sibalis, discloses in claim 5 that it is conventional to impregnate multiple

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drugs in devices for use in delivering bioactive agents for particular applications (col. 4, lines 42-50).

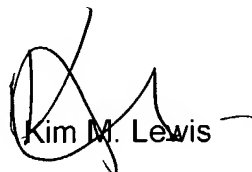
In view of Sibalís, it would have been obvious to one having ordinary skill in the art to modify Matson with the addition of multiple drugs depending on the particular application.

As regards claims 5, 6, 11 and 12, note the rejection of claims 3, 4 and 8, 9 above.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kim M. Lewis whose telephone number is 703.308.1191. The examiner can normally be reached on Mondays to Thursdays from 5:30 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry A. Bennett can be reached on 703.308.0101. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Kim M. Lewis

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Primary Examiner
Art Unit 3743

kml

September 18, 2004